NEGOTIATED RULEMAKING COMMITTEE FOR THE SHARED RISK EXCEPTION

MINUTES[1]

Negotiation Session
July 28-30, 1997
Washington, D.C.

On July 28 through 30, the Department of Health and Human Services (HHS) Negotiated Rulemaking Committee for the Shared Risk Exception held a negotiation session. (See **Attachment A** for a list of appointed Committee Members and alternates who attended the meeting.) The purpose of the meeting was to confirm the Organizational Groundrules, to hear presentations relevant to the rulemaking, to discuss the issues and interests, and to propose options for resolving the issues.

The meeting was noticed in the Federal Register and was open to the public. The meeting was held at the Holiday Inn Capitol, Washington, D.C.

FIRST DAY, JULY 28, 1997

Groundrules:

After reviewing the proposed agenda, the facilitators asked whether there were any questions about the Organizational Groundrules, as revised at the June meeting and explained in the minutes of that meeting. One Member asked whether it is possible to reserve concurrence when neither the appointed member nor the alternate can be there; another asked whether there is the potential for more than one alternate. It was noted that the groundrules developed at the June meeting define consensus as "unanimous concurrence of those present" but do not limit a member to only one alternate. Thus, a party can effectively reserve concurrence by having an alternate present who nonconcurs pending consultation with the Member (although all alternates should be knowledgeable about the subject matter and Committee progress). There was also some discussion of what could

[1] These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

happen with respect to signing an agreement if a member was not present where concurrence was reached on some issues. The importance of getting buy-in on an ongoing basis, in order to get an overall agreement on an interim final rule, was emphasized.

Committee Members present then indicated that they were ready to sign the Organizational Groundrules. One Member later asked for clarification of several provisions. The Committee confirmed its understanding that, if Committee Members sign a written statement indicating consensus, they are not agreeing that none of the members of their association will take any adverse action. In other words, the concept of "party" does not include individual members of an association. In addition, the HHS/IG representative explained the reason for the phrase "Except for the appropriate Federal agencies" in section 4.e. of the Organization Groundrules.

No changes were made as a result of this discussion, and the Organizational Groundrules were signed.

Presentations:

The Committee heard the following presentations:

- How Employer Plans Interface with Medicare and Medicaid - Mark Joffe, Consultant to AAHP

- Risk for Purposes of State Regulation of the Business of Insurance - Fred Nepple and Stephanie Lewis, NAIC

- Risk Sharing in Medicare CHOICES Demonstration Project - Cindy Mason, HCFA

The facilitators then explained how they had grouped issues and interests submitted by Committee Members after the June meeting. The facilitators proposed discussing first the threshold questions listed under the heading "APPROACH" on the issues/interests compilation. No Member objected.

After lunch, the Committee began discussing the threshold questions, referring to the issues/interests compilation.

Discussion: What are the goals/purposes of the anti-kickback provisions and of the exception?

Committee Members identified the following as goals of the anti-kickback provisions:

- Financial goals: reduce overutilization to reduce financial costs

- Consumer protection: prevent risk sharing that might lead to patient harm

- Prevent additional costs to the government:
  - relates to overutilization
  - higher costs due to kickbacks rolled into services/system

- Promote freedom of choice (versus interfering with beneficiary choice)
  Freedom of choice guaranteed by Acts not be compromised by financial arrangements

- Protection against excessive treatment

- Protect competition (due to lock on business)

- Maintain integrity of delivery system

Although there was some disagreement about whether each listed item was in fact a goal of the anti-kickback provisions, the Committee as a whole concurred that the goal underlined above is the most important, or priority, goal.

Committee Members identified the following as goals of the shared risk exception rule:

- Reduce compliance costs

- Avoid interference with developing risk sharing arrangements that benefit the market

- Patient protection (from underutilization)

- To have clarity where possibility of criminal prosecution

- Prevent sham arrangements - Is it "real" risk sharing?

- Define legitimate risk sharing arrangements (significant risk) - to affect provider conduct

The Committee Members concurred that the two items underlined above were the priority goals, but there was some disagreement about other items. Much of the discussion focused on consumer concerns and whether they needed to be reflected directly in the rule. While Members generally agreed that consumer issues are important, they also recognized that concerns that are adequately addressed elsewhere in statute or regulations need not be addressed directly in this rule.

Discussion: Should the rule contain detailed definitions of some/all of the terms or set out general/subjective criteria/standards?

The discussion of this question indicated a tension between the goal of having a clear rule (needed both for enforcing the law and for reducing legal costs of compliance) and the goal of having a rule which allows flexibility to develop new and beneficial arrangements in a rapidly changing marketplace. While conceding that detailed definitions might provide clarity, some Members expressed concern that such definitions would soon become outdated so a new rule would be needed. Some Members strongly objected to the use of numerical percentages as inadequate to protect beneficial arrangements.

One Member noted that, even if detailed definitions would not cover all beneficial relationships, this did not mean that those relationships would be prosecuted as anti-kickback violations. Others responded that providers want to know that their relationships are protected and that lack of such assurance has a chilling effect on providers who otherwise might agree to share risk.

Some suggested a presumption that risk sharing arrangements are protected unless certain factors are present. Others took the position that, given the difficulties in prosecuting under the anti-kickback provisions, including meeting the burden of proof, there is effectively such a presumption already.

Discussion: Should the Committee focus first on substantial financial risk sharing?

Those suggesting that the Committee should start by discussing what is substantial financial risk sharing explained why. While some Members preferred to start discussing other issues, it was agreed that (after discussing the threshold questions) the Committee would have an initial discussion on substantial financial risk to explore the different perspectives, followed by a discussion of other issues.

Discussion: What other policy issues arise?

Committee Members who had identified other issues as policy matters that the Committee needed to decide explained why. Such issues include: 1) whether downstream arrangements will be protected; 2) whether the phrase "individual or entity providing items or services or a combination thereof" should be interpreted narrowly or broadly; 3) how to consider the unique and differing needs of local markets; and 4) whether the exception applies to all Medicare enrollees even if not enrolled under a particular class of contract.

Discussion: What other information/examples does the Committee need first?

Committee Members indicated generally that at some point it would be helpful to develop case studies of risk sharing arrangements to focus discussion of the issues.

Discussion: How if at all, should related rules/guides be taken into account?

The Committee listed the following as related provisions of law, regulation, or guidelines:

- antitrust policy statement
- physician incentive rules
- Stark rules
- 42 U.S.C. 1320a-7a(b)(1)
- State insurance regulation
- PSO legislation
- Other quality control requirements in law or contract
- State anti-kickback laws

Some Members expressed the opinion that the shared risk exception rule should be "consistent" with some or all of these other provisions, or that these provisions should

be taken into account. Others said that the focus should be on developing a rule that makes sense in the context here, rather than on "matching" the terms of this rule to that of other provisions.

The meeting adjourned about 5:00 p.m.

SECOND DAY, JULY 29,1997

The Committee began the second day of the meeting by discussing the concept of substantial financial risk sharing.

Discussion of "substantial financial risk":

One Member began by referring Members to the May/June issue of Health Affairs for statistics on managed care, indicating 50% capitation. He also presented to the Committee the dictionary and Black's Law Dictionary definitions of "substantial" and "risk." He identified three points he considered important: 1) the plain dictionary meaning of "substantial" should be used; 2) risk should be measured from the point of view of the person assuming the risk; and 3) financial risk includes more than revenue.

His first point was opposed by other Members who said that the term "substantial" does require further definition since there is no common understanding of the term, there is a need for clarity, and otherwise people making kickbacks could easily claim they thought their risk was "substantial." These Members also said that 1) Congress directed that standards be established through negotiated rulemaking; 2) Congress rejected proposed legislation that would have had no further definition by regulation; and 3) Congress listed factors to be taken into account. Those factors are:

- The level of risk appropriate to the size and type of arrangement;
- The frequency of assessment and distribution of the incentives;
- The level of capital contribution; and
- The extent to which the risk sharing arrangement provides incentives to control the cost and quality of health care services.

Responses included the following: 1) nothing in the legislative history of the exception supports use of a numerical standard or requires detailed definitions; 2) to permit evolution in the marketplace, the regulation should be open-ended, even if it sets out examples; 3) certain providers are nervous about a bright line test since they have difficulty devising one that would protect all relationships that they consider beneficial; 4) the rule could use factors like whether there is clinical integration to determine whether the arrangement is a sham; and 5) what is "substantial" may depend on factors such as the type of provider and how many Medicare/Medicaid patients are served.

One Member indicated that she would be uncomfortable with a test that was "subjective" in the sense that substantiality would be in the mind of the beholder. Another responded that generic standards are not necessarily subjective, noting that a test is considered objective, legally speaking, if a reasonable person, knowing all the factors, would agree with the conclusion.

One Member indicated that, while he respected the concerns of those who may want a "bright line" test, he thought the rule should provide a general description and then use factors to embellish on this, with examples, to give certainty to those trying to comply with the law. Another said that the proper approach is to think of the term "substantial" in light of what it means in terms of anti-kickback: the rule should exempt risk sharing where it is so substantial that overutilization is not a worry.

One Member proposed using the 25% standard in the physician incentive plan (PIP) rule (although he later acknowledged that it was a good question how to apply this to providers other than physicians, where the method of payment is different). He said the PIP rule was a logical place to start since that is the point where you stop worrying about overutilization and start worrying about underutilization. He noted that one Member had indicated earlier that, given the rationale for setting the 25%, it was arguably not set high enough in light of changes in the marketplace since the 25% was calculated.

Others objected to using the PIP rule, asserting: 1) there is a "reasonable middle" not addressed in the PIP rule: an area below the threshold where there is still an incentive not to overutilize; 2) the PIP rule is different because it covers just referrals and just

physicians; 3) the PIP rule is based only on theory, not on performance, since there is no information to suggest a connection between incentives and quality of care; and 4) Congress recognized that one percentage measure would not be appropriate for all types of providers.

One Member suggested that having specific definitions would be less important if other measures are in place to protect the patients and programs, such as quality control, utilization review, and patient satisfaction. Others agreed, but one Member said that utilization review controls are not sufficient alone to meet the goal of the anti-kickback law because they cannot detect lower levels of overutilization (such as one extra test here or there) which still affect program costs.

One Member asked why not adopt the suggestion to define risk sharing as presumptively legal, as opposed to presumptively illegal, given the broad terms of the anti-kickback law. The response was that the anti-kickback law is much the same as the Sherman Act: the terms are broad, but the application is narrow, and prosecutors use a rule of reason for behavior outside of the safe harbors. This led to a discussion about whether the new advisory opinion process is equivalent to case law in the antitrust area in developing a rule of reason, given that advisory opinions are not precedential, but do contain method and analysis. One Member asked how he could advise constituents if he did not know whether an arrangement would be prosecuted, indicating that he needed guidance on what analysis prosecutors would engage in. Another indicated that the need for clarity regarding what will be considered an illegal arrangement is greater now because civil money penalties (with a lower standard of proof) are available to prosecutors and because of whistleblower suits.

One Member suggested that the question of whether risk is "real" is different from the question of whether it is "substantial" and that Committee Members could probably make progress on the question of what is "real" since they have a sense of what is outside the mainstream.

Another suggested that the Committee leave the concept of "substantial" alone for a while and talk about "risk."

Discussion of risk:

The Committee then generated a list of issues under the heading "Risk for cost or utilization of items or services or a combination that individual or entity is obligated to provide":

- measure of anticipated margin, cost - not revenue
- timing critical (must establish standards)
- "risk for cost" could include how to cost out your service
- a company like a utilization review company may be appropriate to be at risk - obligated to provide services
- risk of material enough nature to not provide an incentive to overutilize
- potential for underutilization
- "obligated" attached to what agreement requires (downstream arrangements)
- "cost or utilization" is cost to the organization
- "risk" is accountability to patient (not only financial but management) and includes cost to government
- measure expenses to revenue (match)
- "obligated" means control or responsible for
- cost relates to efficiency
- obligated relates to control - question: Do bonus arrangements apply?
- many ways can be at risk depending what at risk for
- risk should include reward
- threshold should be lower for entities having less control
- include downstream risks and arrangements but not lock into today's arrangements
- risk occurs at point where providing additional services does not result in financial gain
- when reach point where no incentive to overutilize doesn't start incentive to underutilize - middle point
- risk is exposure for cost of care (overall)
- medicaid: risk begins above capitation (expenses>revenue)
- risk occurs when take the risk for potential loss
- for services or viability of organization? - for contract not overall viability of enterprise

- how real is risk? Look at how losing contract is being handled (disenroll) Enter into a bad deal knowingly is not real risk
- standards for measuring items/services/utilization (as part of arrangements)
- NOT bottom line no additional cost to government - work Quality of Care into formula once no gain but risk of loss
- whether FFS arrangements can ever be at risk
- the more items/services provider provides, the less money he gets
- "obligated" means services provided by that provider directly (ss statute) (PIP refers to services "ordered")
- risk sharing relates to relationship between revenue and expense (anticipated and actual) tied to what risk share is obligated under your contract
- items or services provided to our beneficiaries (not others)

To focus the discussion, one Member drew on the flipchart a hypothetical arrangement in which a managed care organization (MCO) -- BCBS in the example -- provides a capitation payment to a nursing facility (NF), which in turn shares risk with a therapy company (TH). In this hypothetical, BCBS receives a $100 capitation amount from the payor and pays $97 of that amount to the NF. Discussing this hypothetical raised the following questions:

- Assuming there is risk sharing both between BCBS and NF and between NF and TH, is the relationship between NF and TH potentially protected? -- Is NF an "organization" for purposes of the second part of the shared risk exception?

- Is the relationship between BCBS and NF a "risk sharing arrangement"? Is capitation always risk sharing? Is "risk transfer" different from "risk sharing"? Does "risk sharing" include only situations where parties share in a risk pool? Does BCBS retain risk in the hypothetical since BCBS is obligated to the payor to provide the services even if NF goes bankrupt? Does it matter whether BCBS retains the $3 solely to cover administrative costs, or for other purposes?

The hypothetical also raised the question whether, assuming the payments between NF and TH are on a fee-for-service (FFS) basis, the arrangement between NF and TH should be protected because it is "downstream" from the capitation arrangement between BCBS and NF, and the program pays only $100 no matter how much services are provided by TH. Explaining why she thought the arrangement between NF should not be protected (if FFS), one Member indicated that 1) even if the $100 capitation payment represents a limit on program costs for services TH provides in year X, a kickback from TH to NF leading to overutilization of the therapy services could result in increased reported costs that would be used to set future capitation payment amounts and therefore ultimately increase program costs; and 2) a kickback from TH to NF would raise quality of care concerns.

Before lunch, the Committee agreed generally that more hypotheticals would be helpful. After lunch, some plan and provider Members proposed that they caucus in the afternoon to develop hypotheticals to present to the Committee the next day. Accordingly, the Committee adjourned for the day at about 2:00, agreeing to reconvene at 8:30 a.m.

THIRD DAY, JULY 30, 1997

Discussion of hypotheticals:

In the morning, five hypothetical managed care arrangements were described by plan Members, with assistance from Mark Joffe and from provider Members. The hypotheticals were illustrated on flipchart sheets. Hypotheticals I, II, and V are recreated as **Attachments B, C, and D** to these minutes. Hypothetical III was the same as I, except with the MCO qualifying as a § 1876 eligible organization reimbursed on a risk basis. Hypothetical IV was the same as I, except with the MCO qualifying as a § 1876 eligible organization reimbursed on a cost basis. Mark Joffe indicated that there were two goals of the hypotheticals: to give a basic understanding of how the arrangements work and to identify what motivates parties to enter into these arrangements. He noted the following broad points: 1) there are an infinite number of models; 2) this is a moving target, changing each year; 3) many terms of the arrangements are market-driven; and 4) there is

substantial state oversight, unless the MCO is just administrative and assumes no risk.

Discussion topics included the following: 1) differences where Medicare is secondary or primary payor; 2) incentives that do or do not affect the ways physicians practice; 3) differences in arrangements caused by differences in the nature and maturity of the local marketplace; 4) the pressure on each participant to add value (quality and reduced cost) since that is what the ultimate payors are looking for; 5) the importance of reliable data (such as data on utilization rates and outcomes) and the role that the ability to produce such data plays in negotiations; 6) the extent to which the typical physician practice is fee-for-service (FFS) or managed care; 7) the extent to which systems set up for managed care affect physician behavior regarding FFS patients (spill-over effect); 8) the extent to which states regulate downstream risk; 9) the trend to move controls down to the local level to pressure physicians to adopt best practices; 10) the effect of formularies on prescription practices; 11) the extent to which physicians are aware of whether a patient is FFS or not; and 12) for physician hospital organizations (PHOs), the extent to which ownership interests of doctors and capital investment by hospitals may be relevant factors in determining whether the shared risk exception should apply.

The Committee also looked at examples of incentive plan terms, provided by Mark Joffe. This discussion led to questions about risk corridors; utilization targets (how they are set and whether they can be manipulated); methods actuaries use to set utilization targets (including experience of the particular plan, ability of the plan to be effective, the geographic area served, and the population to which the plan is being marketed); and the length of time risk sharing arrangements are usually in effect (about five years, depending on the market, but with certain aspects subject to renegotiation or different each year of the contract). Commenting on whether an entity wanting to make a kickback could assume a safe harbor form without the substance, one Member stated that it is in the interest of the MCO to take care that that does not happen. Another commented that there is not enough money flowing through the system to structure such an arrangement.

Future meetings:

After lunch, the Committee discussed dates for meetings after the September 9-10 meeting (which has already been noticed in the Federal Register). Based on Members' calendars, the facilitators asked Members to set aside **Monday, October 6 through Friday, October 10** (with exact dates to be determined later based on further information, at the request of a Member), **November 19-21**, and **December 16-18**. The facilitators transmitted a request from a prescription benefit management company to make a 45-minute oral presentation at the September meeting. The Committee decided that the oral presentation should be limited to five minutes, consistent with the opportunity offered for other oral statements to the Committee from the general public. Committee Members noted that a written statement could also be submitted and that the Committee could ask for further information if it needed it.

Agenda items identified for the September meeting included sharing information about the recent legislation concerning "provider sponsored organizations" and discussing the primary issues by considering options for resolving those issues generated by Committee Members (see below).

Identifying "primary issues" to be addressed:

The following "primary issues" were identified and grouped by the Committee. Grouped items each have the same symbol preceding them.

* Does the language of the law (exception) cover anything but the top relationship between MCO and first level contractor?
* If exception only applies to the first tier, is everything below a kickback?
* What constitutes an "organization"? (Can it be a provider? an IPA?)

> Does the exception cover anything other than what the provider provides directly?
> Do the items or services need to be "necessary" and do they have to be specifically listed in the written agreement to be subject to the exception?
> Items and services . . . "obligated to provide"-- is it by contract or by statute?

> Who is an entity or individual providing services . . and do the services need to be medical in nature or can they be other?

Q How do you incorporate the evaluation of quality in IV [of the factors to consider] into the criteria for "substantial financial risk"?
Q Integration of "downstreaming" and quality of care as criteria
Q Is quality of care an anti-kickback concern?

- Is "substantial financial risk" interpreted broadly (generalized test) or narrowly (bright line test)?
- Can "substantial financial risk" be defined in nonnumerical terms to allow flexibility in MC arrangements but preserve not encouraging overutilization?
- What is the effect of pooling risk on whether it's "substantial financial risk"?

D What's the significance of "or a combination" thereof?

+ What is "risk sharing"? [Does] straight capitation sufficiently constitute risk sharing?
+ What is a risk sharing arrangement?

- How does resolution of any of these issues create a bias to (certain) small groups of providers?

@ To be covered by the second prong [of the exception], must the specific items or services provided be covered by a risk sharing arrangement?

What constitutes a "written agreement" (terms, s.a. services, duration . . .)?

~ Difference, if any, between withhold and bonus

Discussion of several "primary issues":

The Committee then chose several of these issues to discuss, reaching consensus on two and generating options for resolving a third, as indicated below. Some Members indicated that they thought the consensus statements needed refining. The facilitators indicated that the consensus could be considered consensus on broad concepts, with exact language to be worked out later,

consistent with the format and organization of any draft rule developed (consensus in principle).

Issue: What's the significance of "or a combination thereof"?
Consensus: The significance of "or a combination thereof" is that the risk can be for items, services, or both.
Issue: Items or services . . . "obligated to provide"--is it by contract or by statute?
Consensus: "Obligated to provide" means obligated by the written agreement.

Issue: Does the exception cover anything other than what the provider provides directly? Is referral itself a service?
Options:

- Only what the provider provides directly or is financially responsible for (subcontract).
  Example: What's not covered is where the physician incentive plan takes into account what's ordered from a laboratory or hospital.

- Whatever the provider
  - provides directly
  - is financially responsible for
  - can be rewarded for
  Example: incentive arrangement where [the incentive is] tied to utilization of hospital services

With respect to the options for this issue, a proponent of the first option indicated that the statutory language could be interpreted only that way. A proponent of the second said that physician services such as referring a patient for laboratory services or admitting a patient to a hospital could be considered services that the physician is obligated to provide when they are medically necessary for the patient. A different interpretation, he said, would put a chill on physician risk arrangements and lose the benefits from incentives that affect physician behavior.

Developing options for the next meeting:

The Committee decided that it would be useful if Members (or groups of Members) developed options to resolve the identified primary issues that could be discussed at the next meeting. The facilitators suggested that the

options be stated as broad concepts, to avoid disputes over wording at this stage. Members may present additional options at the meeting, but **if Members want their options sent out to other Members before the meeting they should submit the options to the facilitators by August 22, 1997**, at the latest. Options will not be attributed to specific Members.

The meeting adjourned at about 3:00 p.m.